California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person: Patricia Harris
(916) 574-7910

ENFORCEMENT COMMITTEE MEETING

William Powers, President and Chair
Stan Goldenberg, RPh.

June 20, 2006
9:30 a.m. – 12:30 p.m.

Radisson Hotel Sacramento
500 Leisure Lane
Sacramento, CA 95815
(916) 922-2020

Meeting Materials

Agenda Item A
Review of Strategic Plan – Enforcement Goal and Strategic Objectives/Activities for 2006-2011

Agenda Item B
Presentation of Prescription Error Data from 1999-2006

Announcement of a Public Meeting of the Drug Enforcement Administration (DEA) and Department of Health and Human Services to Discuss Electronic Prescriptions for Controlled Substances

Agenda Item C
New Federal Requirements Regarding the Sale of Pseudoephedrine and Ephedrine –Containing Products

Workgroup on E- Pedigree
Report from the California Pedigree Working Group (Available June 16, 2006)
California Working Group Q&A (May 2006)

FDA Announcement Regarding New Measures to Protect Americans from Counterfeit Drugs
FDA Counterfeit Drug Task Force Report – 2006 Update

AGENDA ITEM A

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: June 8, 2006

From: Virginia Herold

Subject: Strategic Plan Update

At the April Board Meeting, the board updated its strategic plan. However, several key tasks remain to finalize the new plan, which should be reviewed by the board at the July Board Meeting.

Each of the board's strategic committees is being asked to review and update the respective committee's segment of the strategic plan. To do this there are three documents being provided to the committee for its use, approval and/or modification:

- The Enforcement Committee's goal ("Exercise Oversight on All Pharmacy Activities") and five strategic objectives. Also on this document, there are some activities listed that will achieve the respective objective.
- The board's 12 strategic issues are listed with certain of the corresponding committee's objectives listed by the issue area.
- A goal-alignment matrix that compares the strategic issues by each of the board five goal areas.

Review Requested:

1. Each of the 12 strategic issues needs to be reviewed for content and relevancy. Components may be added or deleted to each of these issue areas.
2. Next, each objective of the Enforcement Committee needs to be reviewed for relevancy under each strategic issue. In some cases, there may be zero overlap between a strategic issue and the objectives of the committee; in other cases all five objectives may appear below a strategic issue. Executive Officer Harris and I have made an initial attempt at assigning objectives for the Enforcement Committee to each of the 12 issue areas.
3. Committee members are asked to consider and recommend strategic activities or initiatives they believe would secure the objectives in an issue area. It may be that no activities are suggested at the time of this review. Opportunities to add such activities could well appear at a future time during the three to five year life projected for this strategic plan. (Executive Harris and I have listed few activities into this framework at this time.)
4. A goal alignment matrix is provided for your reference -- to identify what the board suggested at the April Board Meeting for assignment of issues to each committee's goal area – Goal 1 is the Enforcement Committee's goal.

Goals, Outcomes, Objectives, and Measures

Enforcement Committee

Goal 1:	**Exercise oversight on all pharmacy activities.**
Outcome:	**Improve consumer protection.**

Objective 1.1:	**Achieve 100 percent closure or referral on all cases within 6 months by June 30, 2011:**
Measure:	**Percentage of cases closed or referred within 6 months**
Tasks:	1. Mediate all consumer complaints within 90 days. 2. Investigate all other cases within 120 days. 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Objective 1.2:	**Manage enforcement activities for achievement of performance expectations**
Measure:	**Percentage compliance with program requirements**
Tasks:	1. Administer the Pharmacists Recovery Program. 2. Administer the probation monitoring program. 3. Issue citations and fines within 30 days 4. Issue letters of admonition within 30 days 5. Obtain immediate public protection sanctions for egregious violations. 6. Pursue petitions to revoke probation within 90 days for noncompliance with probationary conditions.

Objective 1.3:	**Achieve 100 percent closure on all administrative cases within one year by June 30, 2011.**
Measure:	**Percentage closure of administrative cases within 1 year**

Objective 1.4:	**Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011.**
Measure:	**Percentage of licensed facilities inspected once every 3 years**
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. 2. Inspect sterile compounding pharmacies annually before renewal or before initial licensure. 3. Initiate investigations based upon violations discovered during routine inspections.

Objective 1.5:	**Initiate policy review of 25 emerging enforcement issues by June 30, 2011**
Measure:	**The number of issues**
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products

STRATEGIC ISSUES TO BE ADDRESSED

Enforcement Committee

1. Cost of medical/pharmaceutical care

Providing necessary medication for all Californians is a concern; there is an increasing demand for affordable health care services. Also, spiraling medical care and prescription drug costs may influence people to take short cuts on their drug therapy or to seek medications from nontraditional pharmacy sources. Tiered pricing is a global reality. Due to global communication, patients can access drugs at different prices, worldwide. Patients seek lower cost medications from these sources because patients assume that prescription drugs are of the same quality as they are accustomed to obtaining from their neighborhood pharmacies. However, the cost of drugs drives unscrupulous individuals (such as counterfeiters and diverters) as well as conscientious health care providers to operate in this marketplace, the former endanger public health and confidence in the prescription drugs patients take.

Objectives:

1.5: Initiate policy review of 25 emerging enforcement issues by June 30, 2011

2. Aging population

There are increasingly more senior citizens, and that population is living longer. Aging consumers often have decreased cognitive skills, eyesight and mobility. Consequently as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand.

Many senior citizens, who previously may not have had prescription drug insurance coverage, will benefit from the new prescription drug benefit of Medicare that started in January 2006. However, this new benefit has been implemented with significant problems for some seniors, and as a complicated new program, will require public education and perhaps statutory modification.

Objectives:

1.5: Initiate policy review of 25 emerging enforcement issues by June 30, 2011

3. Pharmacists' ability to provide care

The ability of pharmacy to provide optimal care for patients with chronic conditions is being challenged. Drugs are becoming more powerful and it is anticipated that more intervention by pharmacists will be required. The challenge is even greater when consumers fill multiple prescriptions at different pharmacies. The pharmacist shortage, increased consumer demand for prescription drugs, patient compliance in taking medications and polypharmacy are issues which will impact pharmacists' ability to provide care.

Objectives:

1.3 Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011

1.5 Initiate policy review of 25 emerging enforcement issues by June 30, 2011

4. Changing demographics of California patients

The diversity of California's population is growing with respect to race, ethnicity and linguistic skills, as is the segment that seeks drugs and products from foreign countries. This requires greater knowledge, understanding and skills from health care practitioners. The increasing diversity of patients is coupled with culturally-based beliefs that undervalue the need for licensed pharmacists and pharmacies, and instead encourage purchase of prescription drugs from nontraditional locations and providers.

There also is widespread belief that there must be a medication solution for every condition or disease state.

Objectives:

1.5: Initiate policy review of 25 emerging enforcement issues by June 30, 2011

5. Laws governing pharmacists

New laws enhancing pharmacists' roles as health care providers are needed. The laws must address several key issues including: expansion of the scope of pharmacy practice, the ratio of personnel overseen by pharmacists, delineation of the role of pharmacists relative to selling versus nonselling duties of personnel, and the responsibility for legal and regulatory compliance of the pharmacist-in-charge.

Objectives:

1.2 **Manage enforcement activities for achievement of performance expectations**

1.3 **Achieve 100 percent closure on all administrative cases within one year by June 30, 2011.**

1.4 **Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011**

1.5: **Initiate policy review of 25 emerging enforcement issues by June 30, 2011**

6. Integrity of the drug delivery system

Implementation of the e-pedigree for prescription drugs will reduce the growing incidence of counterfeit medications in California's pharmacies. Additionally the federal government has demonstrated an increasing interest in regulating health care to safeguard consumer interests. New legislation and regulation may be created in response to emergency preparedness, disaster response and pandemics. Changes in the prescription drug benefits provided to Medicare beneficiaries will continue to command attention.

Objectives:

1.1 **Achieve 100 percent closure or referral on all cases within 6 months by June 30, 2011**

1.2 **Manage enforcement activities for achievement of performance expectations**

1.3 **Achieve 100 percent closure on all administrative cases within one year by June 30, 2011**

1.4 **Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011**

1.5 **Initiate policy review of 25 emerging enforcement issues by June 30, 2011**

7. Technology Adaptation

Technology will greatly impact the processing and dispensing of medication. Electronic prescribing and 'channeling' to locations other than a traditional pharmacy may become the business model. Automated pharmacy systems and electronic prescribing will impact pharmacy. New methods of dispensing medications raise additional liability issues. New medication, perhaps engineered for specific patients, will become available at high costs and require special patient monitoring systems.

Objectives:

1.5: **Initiate policy review of 25 emerging enforcement issues by June 30, 2011**

8. Internet issues

The availability of prescription drugs over the Internet is on the rise. Multiple and easy access of drugs without pharmacist participation is dangerous. Entities promoting illegal drug distribution schemes have taken advantage of the Internet. Monitoring and protecting the public from improper drug distribution from these Internet pharmacies is severely impaired with continued resource constraints by both the federal and state agencies with jurisdiction.

Objectives:

1.2 Manage enforcement activities for achievement of performance expectations

1.3 Achieve 100 percent closure on all administrative cases within one year by June 30, 2011

1.4 Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011

1.5 Initiate policy review of 25 emerging enforcement issues by June 30, 2011

9. Disaster planning and response

Pharmacists need to be ready to be positioned to provide emergency care and medication in response to natural disasters and terrorism. This requires specialized knowledge, advance planning and integration of local, state and federal resources that can be quickly mobilized.

Additionally, regulatory adjustments to the September 11 terrorism may affect persons' rights to privacy.

Objectives:

1.5: Initiate policy review of 25 emerging enforcement issues by June 30, 2011

10. Qualified staff

The state's fiscal crisis has affected the board's ability to investigate customer complaints or hire staff. The board lost 20 percent of its staff during the prior four years due to the state's hiring freezes. Loss of these staff has altered the provision of services by the board. The salary disparity between the private and public sectors in compensation for pharmacists will make it difficult to recruit and retain pharmacist inspectors. Moreover, for all staff, if wages remain essentially frozen, the retention of current employees could be impacted.

Objectives:

1.1 Achieve 100 percent closure or referral on all cases within 6 months by June 30, 2011

1.2 Manage enforcement activities for achievement of performance expectations

1.5 Initiate policy review of 25 emerging enforcement issues by June 30, 2011

11. Pharmacy/health care in the 21st century

The state's health care practitioners (pharmacists, physicians, nurses) are being influenced by a variety of internal and external factors that affect and will continue to effect health care provided to patients. Improved patient care will result from improved integration among these professions. Also, a renewed emphasis on patient consultation will benefit patient knowledge about their drug therapy and thus improve their care.

Objectives:

1.2 Manage enforcement activities for achievement of performance expectations

1.5 Initiate policy review of 25 emerging enforcement issues by June 30, 2011

12. Information Management

Creation, maintenance and transfer of electronic patient records and prescription orders will be the norm in the future. Patient records need to remain confidential and secured from authorized access. Pharmacies and wholesalers need to ensure the availability of an e-pedigree for drugs obtained, transferred and dispensed. It is likely that all controlled drugs dispensed in California will be tracked electronically by the CURES system.

Objectives:

1.1 Achieve 100 percent closure or referral on all cases within 6 months by June 30, 2011

1.2 Manage enforcement activities for achievement of performance expectations

1.4 Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011

1.5 Initiate policy review of 25 emerging enforcement issues by June 30, 2011

Goal Alignment Matrix – Strategic Issues

	Goal 1: Exercise oversight on all pharmacy activities	Goal 2: Ensure the qualifications of licensees.	Goal 3: Advocate legislation and promulgate regulations that advance the Vision and Mission of BOP.	Goal 4: Provide relevant information to consumers and licensees.	Goal 5: Achieve the Board's Mission and Goals.
Strategic Issues					
1. Cost of medical/pharm-aceutical care	X		X	X	X
2. Aging population	X	X		X	X
3. Pharmacists' ability to provide care	X		X		X
4. Changing demographics of CA patients	X	X		X	X
5. Laws governing pharmacists	X	X	X	X	
6. Integrity of the drug delivery system	X	X	X		
7. Technology adaptation	X		X	X	X
8. Internet Issues	X			X	X
9. Disaster planning and Response	X	X	X	X	X
10. Qualified staff	X	X			X
11. Pharmacy/ Healthcare Integration in the 21st century	X	X	X	X	X
12. Information Management	X	X	X	X	X

AGENDA ITEM B

Attachment 1 – Prescription Error Data Presentation

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: June 12, 2006

From: Patricia F. Harris
Executive Officer

Subject: **Prescription Error Data**

Last year, Senator Speier sponsored Senate Concurrent Resolution (SCR) 49, which passed. SCR 49 created a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers.

On May 19th, I spoke to the panel about the board's quality assurance program and a summary of pharmacy laws that are used to prevent prescription errors such as patient consultation, medication profiles, and drug therapy review.

On June 2nd, I gave a second presentation on prescription error complaints and the board's citation and fine program. I provided data from 1999 through June 1, 2006. I will be presenting this same data at this meeting.

MEMBERS OF MEDICATION ERRORS PANEL

Legislators

Senator Jackie Speier (D) – Staff: Ronald Spingarn, Legislative Consultant
RONALD.SPINGARN@SEN.CA.GOV or (916) 651 – 4008

Senator Sam Aanestad (R) – Staff: Paul Deiro, Chief of Staff
Paul.Deiro@sen.ca.gov or (916) 651 – 4004

Assemblymember Wilma Chan (D) – Staff: John Gillman, Assembly Health Committee Consultant
John.Gilman@asm.ca.gov or (916) 319 2097

Assemblymember Greg Aghazarian (R) – Staff: Gail King-Delihant, Chief of Staff
Gail.Delihant@asm.ca.gov or (916) 319 - 2026

Non-Legislators

Brian Alldredge, Professor Clinical Pharmacy
University of CA, San Francisco
alldredgeb@pharmacy.ucsf.edu
Representing Pharmacy School Faculty

Dorothy (De) Calvert, RN
Kaiser Permanente Medical Group, Roseville
dcalvertrn@usamedia.tv
Representing California Nurses Associates

Ramon Castellblanch, Assistant Professor Health Education
San Francisco State University
ramonc@sfsu.edu
Representing Consumers

Carey Cotterell
Pharmacy Quality & Patient Safety Leader
Kaiser Permanente Medical Care Program (Downey, CA)
carey.c.cotterell@kp.org
Representing California Association of Health Plans

Robert Friis, Professor and Chair
Department of Health Sciences, CA State University, Long Beach
President, Southern California Chapter, American Public Health Association
rfriis@csulb.edu
Representing a public health organization

John Gallapaga
California Health Advocates (HICAP Associates) (Sacramento, CA)
johnpapa@sbcglobal.net
Representing AARP

Merrill Jacobs
Deputy Vice President, State Governmental Affairs
Pharmaceutical Research and Manufacturers of America (Sacramento, CA)
mjacobs@phrma.org
Representing PhRMA

Carlo Michelotti
CEO, CA Pharmacists Association, Retired (Sacramento, CA)
carlo.michelotti@sbcglobal.net
Representing California Pharmacists Association

Gil Preston, JD
Watson Pharmaceuticals (Fullerton, CA)
gpreston@watsonpharm.com
Representing Generic Pharmaceutical Association

Susan Ravnan, Pharm.D., FCSHP, Professor
School of Pharmacy and Health Sciences, University of the Pacific (Stockton, CA)
sravnan@chw.edu or sravnan@pacific.edu
Representing California Society of Hospital Pharmacists

Lorie Rice, Associate Dean
School of Pharmacy, University of California, San Francisco
ricel@pharmacy.UCSF.edu
Representing Consumer Healthcare Products Association

Gurbinder Sadan, MD (Claremont, CA)
Eagle500SL@hotmail.com
Representing California Medical Association

Debbie Veale, Regional Manager
Managed Care Operations, Albertson's, Fullerton
debbie.veale@albertsons.com
Representing California Retailers Association, Chain Drug Committee

Enforcement Committee Meeting
Prescription Errors Presentation
California State Board of Pharmacy

Patricia Harris
Executive Officer
June 20, 2006

Prescription Error Cases

	FY 02/03		FY 03/04		FY 04/05		FY 05/06	
Total Received	329		441		507		337	
Total Closed	228		518		492		397	
Total Substantiated Cases	136	60%	416	80%	367	75%	276	70%
Total Unsubstantiated Cases	92	40%	102	20%	125	25%	121	30%

Closed With Citation & Fine

	FY 02/03	FY 03/04	FY 04/05	FY 05/06
Pharmacists	166	185	155	102
Pharmacies	156	176	172	112

Prescription Error Data

Medication Error Category	1999 – Nov 2003 Number of Citations	Dec 2003 – Jun 2004 Number of Citations	Jul 2004 – Jun 2005 Number of Citations	Jul 2005 – Jun 2006 Number of Citations	Number of Citations / Percent of Total Medication Errors	
Wrong Drug	88	81	55	38	262	42%
Wrong Strength	44	33	43	21	141	23%
Wrong Instructions	21	9	17	11	58	9%
Wrong Patient	12	13	22	17	64	10%
Wrong Medication Quantity	8	7	2	3	20	3%
Other Labeling Error	10	11	7	5	33	5%
Compounding/Preparation Error	7	3	2	3	15	3%
Refill Errors (frequency, timeliness)	5	5	6	3	19	3%
Other (not listed)	10			3	13	2%
Total # Citations for errors (may have more than one category listed)	205	162	154	104	625	100%

PRESCRIPTION ERROR DATA

Citations

Fine Amount	Dec 2003 – Jun 2004 Number of Citations	Jul 2004 – Jun 2005 Number of Citations	Jul 2004 – Jun 2005 Number of Citations	Number / Percent of Total Fine Amounts	
$0	16	17	17	50	12%
$100 - $125	16	43	21	80	20%
$250 - $400	81	63	46	190	47%
$500 - $750	39	18	7	64	16%
$1,000	5	2	1	8	2%
$1,500 - $2,000	0	4	3	7	2%
$2,500	2	2	1	5	1%
Total	159	149	96	404	100%

Medication Error Data

1999 – 2003

Common Look-alike / Sound-alike Errors	
Seroquel 200mg	Serzone 200mg
Aciphex	Aricept
Hydroxyzine	Hydralazine
Zyprexa 10mg	Zyrtec 10mg
Quinine 324mg	Quinidine 324mg
Prinivil 5mg	Proscar 5mg
Celebrex 200mg	Celexa 20mg
Trazodone 50mg	Tramadol 50mg
Elavil 10mg	Enalapril 10mg

MEDICATION ERROR DATA

July 1, 2004 – June 2006

Common Look-alike / Sound-alike Errors	
Clomiphene	Clonazepam
Dynacin	Dynapen
Marinol	Moban
Metoprolol	Metoclopramide
Videx	Vicodin
Fluextine	Paroxetine
Lanoxin	Levoxyl
Prelone	Pediazole
Prilosec	Prozac

Loxapine	Lexapro
Lisinopril	Lovastatin
Lisinopril	Lipitor
Novolin N	Novolin 70/30
Norvasc	Navane
Proscar	Prinivil
Purinthal	Propylthiouracil
Darvocet	Fioricet
Alprazolam	Atenolol
Imipramine	Imitrex

Medication Error Data

July 1, 2004 – June 2006 Continued

Common Look-alike / Sound-alike Errors	
Clorpromazine	Chlorpropamide
Prednisone	Prednisolone
Topramax	Toprol
Mircette	Micronor
Nasocort	Nasolide
Coreg	Cozaar
Norvasc	Namenda
Zyprexa	Zyprexa Zydisc

Hydralzine	Hydrochlorthiazide
Clonidine	Clonazepam
Glipizide	Glyburide
Furosemide	Fluxetine
Lorazepam	Levoquin
Miralax	Maalox
Paxil	Prozac

Prescription Error Cases

$500 Fine

- **Case 1:** An 84 year old woman was prescribed Namenda 10mg for treating Alzheimer symptoms. The pharmacist incorrectly dispensed Norvasc 10mg (a drug to lower blood pressure), which the patient took for 28 days before the error was discovered. The patient showed symptoms of weakness, confusion, low blood pressure, and declined physically.
- **Case 2:** A premature infant weighing 4.3 pounds with respiratory difficulties was prescribed Aminophyllin 25mg/ml (dilate lungs) with directions to administer 1.6 ml or 4mg every 8 hours. The pharmacist miscalculated the dose and the patient received 40mg (10 times) resulting in re-hospitalization. Patient was weaned off the high dose and recovered.
- **Case 3:** A 16 year old male was prescribed Oxycodone 5mg/5ml and to take 5ml to relieve pain. The pharmacist incorrectly dispensed Oxycodone 20mg/1ml and to take 5ml. The patient went into respiratory failure after one dose and was hospitalized. Investigation showed the prescription written by the prescriber was incomplete and did not indicate strength and dosage to be administered. The pharmacist failed to clarify the order prior to dispensing.

Prescription Error Cases

$1,000 Fine

- **Case 1:** A patient with an insufficient thyroid was prescribed liothyronine 9.25 micrograms (a thyroid replacement drug.) The pharmacist incorrectly dispensed liothyronine 9.25 milligrams (1,000 times the prescribed dose). The patient exhibited symptoms of thyroid toxicity such as psychosis, increased heart rate, memory loss and weakness. The patient was hospitalized and taken off the high dose.
- **Case 2:** An 82 year patient was prescribed Cardura (to treat his prostrate cancer). The pharmacist incorrectly dispensed Coumadin (a blood thinner), which the patient took for 9 days before discovering the error. The patient was admitted to a hospital intensive care unit for a severe bleeding disorder. Patient eventually recovered but was hospitalized for a long period of time.
- **Case 3:** A patient was prescribed Clonazepam 2mg (controlled substance used to treat anxiety). The pharmacist incorrectly dispensed Clonidine 0.2mg (used to treat hypertension), which the patient took for 5 months. The patient experienced low blood pressure and had difficulty concentrating. The patient went to the emergency room and was admitted to the hospital for 2 weeks to wean the patient off the medication. The pharmacist was also cited for failure to provide consultation.

Prescription Error Cases

$2,500 Fine

- **Case 1:** A patient was scheduled to have a procedure and was prescribed two drugs: Lorazepam 2mg, take 1 tablet ½ hour before procedure and Promethazine 25mg, take 1 tablet ½ hr before procedure (both drugs are used to reduce anxiety). The pharmacist dispensed the two drugs to take five tablets of each ½ hr before the procedure. The patient experienced a toxic effect and expired from a combination of drugs including the overdose and other drugs used during the procedure. The investigation showed the prescriber had written brackets around the 3 drugs with the directions to take ½ hour prior to the procedure in the doctor's office. The prescription was ambiguous and the pharmacist failed to clarify the order prior to dispensing.

- **Case 2:** During a night shift, a patient in a hospital intensive care unit was prescribed an intravenous infusion containing a drug called phenylephrine (used to raise the blood pressure). The pharmacy technician prepared the infusion but incorrectly used a drug called Phentolamine (lowers blood pressure). The pharmacist failed to accurately verify the drug used by the pharmacy technician to prepare the infusion and the patient went into cardiac arrest and expired. The investigation substantiated the hospital pharmacy's system for verifying drug orders prepared by pharmacy technicians was not followed as well as inadequate staffing patterns (hospital administration refused to add staff to the night shift) which contributed to the Sentinel Event. The hospital and the pharmacist were each fined $2,500.

PRESCRIPTION ERROR CASES

$2,500 Fine

- **Case 3:** A cancer patient was prescribed a drug called Cisplatin at a dose of 50mg, which the patient received 4 times previously. For the most recent dose, the pharmacist incorrectly dispensed Cisplatin 500mg (ten times the prescribed dose). The patient experienced significant side effects with lowering of the blood cells and required transfusions; however the patient died. An investigation revealed the pharmacist failed to clarify the prescription, which the dose was unclear and ambiguous as written by the prescriber.

AGENDA ITEM B

Attachment 2 – Announcement of a Public Meeting of the DEA and Department of Health and Human Services to Discuss Electronic Prescriptions for Controlled Substances

National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Charisse Johnson, Professional Affairs Manager

DATE: June 2, 2006

RE: DEA Announces Public Meeting to Discuss Electronic Prescriptions for Controlled Substances

---

Drug Enforcement Administration (DEA), in conjunction with the Department of Health and Human Services, is conducting a public meeting to discuss electronic prescriptions for controlled substances. This meeting will be held Tuesday, July 11, 2006, and Wednesday, July 12, 2006, from 8:30 AM-5:30 PM. Registration will begin at 7:30 AM. This meeting will be held at the Marriott Crystal City at Reagan National Airport, 1999 Jefferson-Davis Highway, Arlington, VA 22202; 703/ 413-5500. The meeting will take place in the Crystal Forum amphitheatre, adjacent to the hotel.

Specifically, this meeting is intended to allow industry including prescribers, pharmacies, software/hardware vendors, and other interested third parties, to address how electronic prescribing systems can meet DEA's prescription requirements under the Controlled Substances Act, without unduly burdening the parties to electronic prescribing transactions. Persons wishing to attend this meeting, space permitting, must provide attendee information to the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, via e-mail to dea.diversion.policy@usdoj.gov, or via facsimile, 202/353-1079. Persons wishing to attend the meeting must provide this information to the Liaison and Policy Section no later than Monday, June 26, 2006.

DEA will also be accepting written comments on electronic prescriptions for controlled substances until June 26, 2006. Comments may be submitted to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov; written comments sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. To ensure proper handling of comments, please reference "Docket No. DEA-218N" on all written and electronic correspondence.

More information on the public meeting and the specific issues on which DEA is requesting comments can be found in the May 15, 2006, *Federal Register* notice at: http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/E6-7302.htm.

If you have any questions, please contact me via e-mail at cjohnson@nabp.net or via phone at 847/391-4400 or 1-800/774-6227.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

AGENDA ITEM C

National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Melissa Madigan, Professional Affairs Senior Manager

DATE: June 2, 2006

RE: Drug Enforcement Administration Implementation of the Combat Methamphetamine Epidemic Act of 2005

In response to the National Association of Boards of Pharmacy's (NABP) request for information regarding Drug Enforcement Administration's (DEA) implementation of the Combat Methamphetamine Epidemic Act of 2005, DEA is currently drafting regulations to implement the provisions of the Act, and cannot specifically address questions at this time. However, DEA has invited NABP to comment on these regulations once they are published.

For a copy of the Act and the guidance document "General Information Regarding the Combat Methamphetamine Epidemic Act," which gives information regarding effective dates, sales limits, and other requirements, please consult the DEA Web site at www.deadiversion.usdoj.gov.

cc: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control
NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

Federal Limits on Pseudoephedrine-Containing Products

In March, Congress passed new requirements for the sale of all (single and multi-ingredient) pseudoephedrine and ephedrine-containing products. The new law (Public Law 109-177) places ephedrine, pseudoephedrine (PSE), and phenylpropanolamine in a new Controlled Substances Act (CSA) category of 'scheduled listed chemical products'. Drug products containing ephedrine, PSE, and phenylpropanolamine are subject to sales restrictions, storage requirements and record keeping requirements. Some of these requirements, which apply to all sellers of these products, go into effect by April 8th; others require compliance by September 30, 2006.

Effective April 8, 2006	
	3.6 gram daily sales limit
	9.0 gram 30-day sales limit
	All non-liquid forms must be sold in blister packs (with a few exceptions)
	Mail-service pharmacy must verify patient's identification before shipping product
	Mail-service pharmacy 7.5 gram 30-day sales limit
Effective by September 30, 2006	
	Products must be placed behind a counter or in a locked cabinet
	Seller must maintain a written or electronic logbook** which must identify: • the product name • the quantity sold • names and addresses of purchasers • dates and times of sales
	Purchasers must present a photo ID* and sign the logbook
	Sellers must self-certify to the U.S. Attorney General that their sales personnel have been trained as required by regulations (yet to be promulgated)
	7.5 gram 30-day sales limits for mobile sellers (such as kiosks in airports)
* Logbook and ID requirements do not apply to sales of 60 mg or less of pseudoephedrine.	

There are more changes on the horizon. Many of the requirements that go into effect by September 30th will require promulgation of regulations to address logbook and training requirements and ways to address privacy issues that could arise with the logbook. Additionally, the American Pharmacists Association is working to get confirmation from the DEA that the regulations do not apply to prescribed products, including prescribed over-the-counter products.

WORKGROUP ON E-PEDIGREE

Attachment 1 – California Working Group Q&A

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

California Pedigree Working Group
Questions and Answers
May 2006

Regulatory

1. While California is a pioneer in establishing a pedigree model, should a catastrophic event occur, and product cannot be shipped in from outside of the state because of unique pedigree requirements, how will you address the need for emergency shipments into the state?

While the Board of Pharmacy cannot fully predict its response to a hypothetical set of circumstances, B & P §4062(b) gives the board authority to waive application of any provisions of the pharmacy law or regulations during a declared federal, state or local emergency if, in the board's opinion, the waiver will aid in the protection of the public health or the provision of patient care. The board would expect that in the event of a catastrophe, licensees would make every effort to comply with the law as well as meeting patients' needs during an emergency.

2. We expect to have a response from FDA at the end of May on their actions on the temporary PDMA Final Rule Stay. If the stay is lifted, would compliance with the PDMA act satisfy the California Pedigree requirements?

The board cannot comment on the scope of the PDMA, its implementing regulations or its interaction with California law until the exact parameters thereof are decided.

3. As you know, under California Code Section 4163, "A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree" and "A wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree". Additionally, the statute allows the Board to extend the date for compliance with the requirement for **manufacturers or wholesalers** until January 1, 2008, and enables the Legislature to separately extend the date for compliance with the requirement for a pedigree for **pharmacies** until January 1, 2009. It is our understanding that some pharmacy groups believe that the initial implementation requirement (January 1, 2007) does not apply to that segment of the industry, but rather, the implementation deadline for pharmacies occurs one year after that for manufacturers and distributors. Could the BOP please clarify whether this is, in fact, the case, and if so, where this is addressed in California law?

Compliance as to all participants in the supply chain for implementation of the electronic pedigree is January 1, 2007. SB 1476 has been introduced to extend the compliance date to January 1, 2008.

Manufacturers

4. We would expect that for co-license manufacturers, that the billing organization would be responsible for fulfilling the pedigree requirements, although the definition of manufacturer is slightly different. The e-Pedigree should be created from the "Proof of Sale" data elements that are provided to wholesalers by the manufacturer. If the manufacturer is required to create the e-Pedigree, the contractual manufacturing party that introduces the finished and labeled prescription drug product into interstate commerce should be responsible for creating the e-Pedigree. Can you please provide us with an opinion on what is acceptable to the BOP?

A wholesaler or pharmacy may not acquire a prescription drug without receiving a pedigree. Any manufacturer from which the prescription drugs are acquired must initiate and provide the pedigree.

Ownership

5. Our position is that intra-company transfers must be exempted from the pedigree requirements; which is consistent with Federal law under the Prescription Drug Marketing Act. Examples include National DC to Regional DC; or a repackager to DC, where both are owned by same legal entity. How will this be addressed since a change in ownership may or may not always coincide with a change in possession?

A pedigree is required to contain information regarding each transaction resulting in a change of ownership of a given prescription drug.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

6. We do not believe that when a product is shipped via a store-to-store transfer in the retail pharmacy environment (in support of stock shortages), with each store being owned by the same company and the product being transferred via company-owned vehicles, that it constitutes a 'change in ownership'. The BOP has stated that 'change of ownership' is not given a specific meaning in the statute but should there be confusion, that it will review the situations on a case-by-case basis. Can you please provide clarification on the specific steps that must be taken to inform the Board that a determination of ownership needs to be discussed? Should a transfer take place between two stores in a rural community setting where ownership is not the same, are

these one-off exchanges required to generate a pedigree or will proof of delivery suffice?

A pharmacy is required to provide a pedigree as part of any transaction resulting in a change of ownership of a given prescription drug, including but not limited to when the pharmacy returns a prescription drug to the wholesaler or manufacturer from which the prescription drug was obtained, when the pharmacy wholesales the prescription drug to another pharmacy to alleviate a temporary shortage, when the pharmacy transfers the prescription drug to a health care provider authorized to purchase prescription drugs, or when the pharmacy sends a prescription drug to a reverse distributor. The pharmacy is required to provide a pedigree at the time of any sale, trade or transfer of a prescription drug resulting in a change of ownership.

A pedigree is not required if the transaction does not result in the change in ownership of the prescription drug. However, the transaction must be one of the transactions authorized by B& P § 4126.5.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

7. We believe that when a retail pharmacy chain operates a Central Fill operation, the pedigree should end once the product is in the possession of the company that owns/operates the central fill. By way of example, if the drug that is being filled through a Central Fill operation is sent to the chains' pharmacy by the chain DC, the pedigree would stop at the chain DC. If the product is received from a distributor, then it would stop at the pharmacy that is doing the Central Fill. Can the Board provide guidance on the interpretation of this situation?

The pedigree for a prescription drug ends with the pharmacy that fills the prescription.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Interstate Distribution

8. We believe that the first point in the pedigree cycle begins at the domestic shipping point of the manufacturer (for those outside of the United States). Is the shipping point you refer to in your guidance the foreign manufacturing location or the domestic shipping point?

The manufacturer must initiate the electronic pedigree. A wholesaler or pharmacy cannot acquire a prescription drug without the pedigree.

9. Our understanding is that any product shipped out of California to another state that may not support an electronic pedigree, must be accompanied by a paper pedigree. Can you please clarify the provisions for providing paper pedigrees? Are there specific guidelines for generating and maintaining paper pedigrees for product that may return to California?

California pharmacy law applies to prescription drugs shipped into California.

Pedigree Association

10. One definition of the inference concept is the ability to infer that a product contained in a sealed case would be associated with, and covered under, the same pedigree as all other contents of the same case. Once a case is broken out, and the units are no longer with case, pedigree information will be determined through the inference model unless serialization of each unit is in place. Given that the goal is to be able to associate an item to a pedigree (parent-child hierarchy), what is the Board's position on using the inference model, and would serialization be a long-term goal?

The Board of Pharmacy is not familiar enough with the tern "inference concept" or its application to comment on its possible application in every scenario. It is not clear how the "inference concept" would accomplish the statutory requirement of pedigree documentation for each prescription drug. The statute does not specify how such pedigree documentation for each prescription drug is to be accomplished, whether it is by product serialization, NDC number or by some other methodology.

Technology and Data Management/Availability

11. In the situation where a received product is valid, yet system issues prevent the reading or updating of the pedigree (interoperability, damage, etc.), what provisions will be in place to allow the receiver to retain/sell/distribute the product further? Also, when considering liability in these situations, will there be provisions put in place to assist the industry?

The Board of Pharmacy cannot comment on hypothetical factual circumstances that may come before it for a decision at a later date.

WORKGROUP ON E-PEDIGREE

Attachment 2 – FDA Announcement and FDA Counterfeit Drug Task Force Report – 2006 Update

FDA News

FOR IMMEDIATE RELEASE
P06-78
June 9, 2006

Media Inquiries:
301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Announces New Measures to Protect Americans from Counterfeit Drugs

The U.S. Food and Drug Administration (FDA) today announced new steps to strengthen existing protections against the growing problem of counterfeit drugs. The measures, which were recommended in a report released today by the agency's Counterfeit Drug Task Force, emphasize certain regulatory actions and the use of new technologies for safeguarding the integrity of the U.S. drug supply.

"The adoption of the FDA Counterfeit Drug Task Force's recommendations will further reduce the risk that counterfeit products will enter the U.S. drug distribution system and reach patients," said Dr. Andrew C. von Eschenbach, the FDA's Acting Commissioner. "We must remain vigilant in our efforts to ensure our nation's drug supply is protected against an increasingly sophisticated criminal element engaging in a dangerous type of commerce."

Among other new measures, FDA will fully implement regulations related to the Prescription Drug Marketing Act of 1987, which requires drug distributors to provide documentation of the chain of custody of drug products -- the so-called "pedigree" -- throughout the distribution system. FDA had placed on hold certain regulatory provisions because of concerns raised at the time about the impact on small wholesalers. Most recently, in early 2004, FDA delayed the effective date of certain regulatory provisions regarding pedigrees to allow the industry time to adopt electronic technology for tracking drugs through the supply chain. Based on information from drug supply stakeholders, the FDA had expected this technology to be in widespread use in the drug supply chain by 2007, but it now appears that these expectations will not be met. Further, FDA has not heard that the concerns raised in the past regarding the impact on small wholesalers remains, and in fact, FDA was encouraged by most drug stakeholders to allow the hold to expire. Doing so would also provide clarity in the drug supply chain regarding who is and is not required to pass a pedigree. Continuing the hold would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices. FDA has, therefore, determined that it can no longer justify not implementing these regulations.

Accordingly, the hold, which will expire in December, will not be continued.

A potential new measure to safeguard the drug supply is the use of electronic track and trace technology, such as radio-frequency identification (RFID), which creates an electronic pedigree (e-pedigree) for tracking the movement of the drug through the supply chain. The FDA had expected this technology to be in widespread use in the drug supply chain by 2007. In early 2004 FDA delayed the effective date of the regulatory provisions regarding pedigrees to allow the industry time to adopt this technology. However, it now appears that FDA's expectations for adoption of the technology by 2007 will not be met. FDA therefore has determined it can no longer justify delaying implementation of the pedigree regulations.

Consistent with recommendations of the Task Force, FDA also announces that, during the next year,

its enforcement of the pedigree regulations will focus on products most susceptible to counterfeiting and diversion. FDA intends to announce in the *Federal Register* the availability of a draft compliance policy guide for public comment describing this enforcement approach. By providing guidance on the types of drugs that are currently of greatest concern to FDA, the agency intends to give wholesale distributors a better idea on where and how to focus their initial energies to come into complete compliance with the regulations (21 CFR Part 203) for all the prescription drugs they distribute. The draft guidance clarifies how FDA intends to prioritize its pedigree-related enforcement resources in 2007. FDA may, under appropriate circumstances initiate regulatory action, including criminal prosecution, for pedigree violations that do not meet the factors listed in the guidance.

The Task Force report also underlines the agency's belief that widespread use of e-pedigrees using electronic track and trace technology, including RFID, would provide an electronic safety net for our nation's drug supply. The report therefore recommends that stakeholders continue to work expeditiously toward that goal, and that their implementation of RFID technology be used first on products most susceptible to counterfeiting and diversion.

Additional subjects discussed in the Task Force's report include the following key issues related to electronic track-and-trace that are in need of resolution:

- Technical aspects of the mass serialization of marketed drugs by assigning a unique identifier or serial number to each drug package as the initial step in development of track and trace technology.
- Importance of a nationwide universal drug pedigree with uniform information in preference to state laws imposing different pedigree requirements.
- Protection of consumer privacy to prevent unauthorized disclosure of information stored in RFID tags when RFID-tagged drug products are dispensed to consumers.
- Consumer education about RFID and the labeling of RFID-tagged drug products, to disclose to consumers when they are receiving RFID-tagged products and to inform consumers of the benefits of RFID technology and how consumers' privacy is being protected.

The new FDA report is largely based on the Task Force's recent findings in numerous contacts with stakeholders, including a February, 2006 public workshop, request for public comment and monitoring of the latest technological developments.

Today's Task Force report is the third in a series of documents exploring the means of ensuring the safety of the U.S. drug supply. The first report, issued in 2004, outlined the framework for protecting the public from counterfeit medicines, and the second report, released last year, assessed the progress toward implementing the 2004 recommendations. All Task Force Reports are posted on FDA's Web at www.fda.gov/counterfeit .

####

THE HENRY J. KAISER FAMILY FOUNDATION kaisernetwork.org

Kaiser Daily Health Policy Report

Monday, June 12, 2006

Prescription Drugs

FDA Will Begin Enforcing Anti-Counterfeiting Law In December

As expected, FDA on Friday announced that it soon will begin enforcing a 1999 federal rule requiring pharmaceutical wholesalers to track the supply chain movement of the drugs they distribute, the *New York Times* reports. The rule, which aims to reduce drug counterfeiting, was designed to implement a tracking requirement established in a 1988 law, but FDA has "repeatedly" stayed the rule because the pharmaceutical industry said it lacked the technology to track all of its products, the *Times* reports (Feder, *New York Times*, 6/10). Under the rule, which will take effect Dec. 2, wholesalers will have to supply a "pedigree" tracing every entity that has handled drugs since they left their manufacturers. The pedigree, which can be in paper or electronic form, will include addresses and the lot number of the drugs. FDA said that for the first year the law is in effect, the agency will implement enforcement based on a drug's market value, whether it is used to treat a particularly serious condition and its history of counterfeit concerns. The new law does not apply to wholesalers who have been designated as "authorized distributors" by drug manufacturers, so it primarily will affect secondary wholesalers (*Kaiser Daily Health Policy Report*, 6/9). Randall Lutter, FDA associate commissioner for planning and policy, said the decision to lift the stay "is intended to provide [a] push" to encourage wholesalers to adopt a tracking technology known as radio frequency identification (*New York Times*, 6/10). FDA recommended that wholesalers use RFID, which creates an electronic pedigree, but the agency is not requiring them to do so. The agency recommended RFID first be implemented on products that are most susceptible to counterfeiting (Carey, *CQ HealthBeat*, 6/9).

Technology

RFID tags can be embedded in the labels of drug bottles and packages and scanned like bar codes. However, the tags store more information than bar codes and can be scanned from further away. In addition, unlike bar codes, several of them can be scanned simultaneously. However, "development and adaptation of radio tags have been slowed by concerns on cost, reliability and security," the *Times* reports. In 2003, the Department of Defense, major retailers such as Wal-Mart and manufacturers such as Procter & Gamble agreed to standards for the tags and to push for increased adaptation, but they have mostly implemented the technology only for use on pallets and cartons, rather than for individual drug bottles. In addition, advocates for the technology say the drug industry must agree on which of two competing frequency standards to use before RFID can be more widely implemented. The drug industry has been testing RFID using older, high-frequency systems, but Wal-Mart and other large RFID users use newer, ultra high-frequency bandwidths. A coalition of RFID companies is trying to persuade drug makers to switch to UHF bandwidths (*New York Times*, 6/10).

Comments

Acting FDA Commissioner Andrew von Eschenbach said, "We must remain vigilant in our effort to ensure our nation's drug supply is protected against an increasingly sophisticated criminal element engaging in a dangerous type of commerce." Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, said that the new policy would "provide additional protections and certainty to the supply chain" but that "there is no single magic bullet to prevent counterfeit drugs

from entering the nation's pharmaceutical supply chain" (*CQ HealthBeat*, 6/9). Jeff Steinberg, an analyst for Ernst & Young, said smaller secondary wholesalers are opposed to the new policy because they are concerned it could affect their profits. "This is going to cause a lot of them to cry out in grief," he said, adding, "They are going to have to take some extra steps to determine the drugs have come from a good source, that it was legitimate, that it was stored properly." Author Katherine Eban, who wrote a book about counterfeit drugs, said, "It is a good half-step. Almost every single counterfeit drug that has gotten into a retail pharmacy has come from the secondary market through authorized distributors, who ostensibly 'launder' the origin of the drugs" (Jordan, Newark *Star-Ledger*, 6/10).

Broadcast Coverage

ABCNews' "World News Tonight" on Friday reported on FDA's announcement. The segment includes comments from Margaret Glavin, FDA associate commissioner for regulatory affairs, and Rick Roberts, an HIV-positive U.S. resident who received a counterfeit fertility drug instead of his medication to treat unintended weight loss associated with HIV/AIDS (Stark, "World News Tonight," ABCNews, 6/9). A related ABCNews story is available online. Video of the segment is available online.

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville MD 20857

DATE: June 8,2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Margaret Glavin
Associate Commissioner for Regulatory Affairs

FROM: Andrew vonEschenbach, MD
Acting Commissioner of Food and Drugs

Thank you for submitting to me the Counterfeit Drug Task Force Report - 2006 Update. I strongly concur that increasing the safety and security of the nation's drug supply and protecting it from the increasing sophisticated threat of counterfeit drugs is critically important. I commend you and the rest of the Counterfeit Drug Task Force on your efforts in developing this report and its recommendations to further this goal. I appreciate the fact-finding efforts that the Task Force undertook, such as holding the February 2006 public workshop and soliciting public comment, to understand the issues and provide me with informed recommendations.

I endorse the report and its recommendations. This includes the recommendation not to further extend the stay and to issue a compliance policy guide (CPG) that discusses FDA's enforcement focus regarding pedigree requirements. Please move forward with these recommendations, pursuant to FDA's good guidance practice (GGP) process (21 CFR § 10.1 15), as appropriate.

Andrew C. von Eschenbach, M.D.

FDA COUNTERFEIT DRUG TASK FORCE REPORT:
2006 UPDATE

I. INTRODUCTION

This report is based on the work of the Food and Drug Administration's (FDA or Agency) Counterfeit Drug Task Force.[1] It is the third report issued by the Agency since 2004 to address FDA's and the private sector's response to the emerging threat of counterfeit drugs entering the U.S. drug supply. This report contains recommendations to FDA's Acting Commissioner regarding actions that the public and private sector can take to further speed the adoption of electronic track and trace technology and for the use of pedigrees in general, to increase the safety and security of the U.S. drug supply.

After discussing the background and public comment on the issues addressed in this report, we discuss our recommendations or conclusions regarding:

- The expiration of the stay of 21 CFR §§ 203.3(u) and 203.50;
- The extent to which electronic track and trace technology is being used across the supply chain for electronic pedigrees and the use of radio-frequency identification (RFID) for drug products in the drug supply chain; and
- Technical issues related to the implementation of electronic track and trace technology, such as mass serialization, universal and uniform pedigrees, data management, and privacy issues.

II. BACKGROUND

A. The Counterfeit Problem

Counterfeit prescription drugs are illegal, generally unsafe, and pose a serious threat to the public health. Many are visually indistinguishable from authentic drugs. As we stated in our first Counterfeit Drug Task Force report in 2004 (2004 Report),[2] we believe that counterfeiting is quite rare within the U.S. drug distribution system because of the extensive scheme of federal and state regulatory oversight and the steps taken by drug manufacturers, distributors, and pharmacies, to prevent counterfeit drugs from entering the system. However, we are concerned that the U.S. drug supply is increasingly vulnerable to a variety of increasingly sophisticated threats. We have witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels over the years.

B. The 2004 Counterfeit Drug Task Force Report & 2005 Update

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act (PDMA).[3] This framework called for a multi-layer approach to address the problem and included the following measures:

- Secure the ***product and packaging***
- Secure the ***movement of drugs*** through the supply chain
- Secure ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

In order to implement these measures, the Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the PDMA should be delayed until December 1, 2006 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

In 2005, the Task Force issued an annual update report (2005 Report)[4]. The 2005 Report assessed FDA's and industry's progress toward implementing the 2004 recommendations. In the 2005 Report, the Task Force found, among other things, that:

- Stakeholders had made significant progress in developing and implementing RFID during the previous year;
- FDA was encouraged by the progress stakeholders, standard-setting bodies, and software and hardware companies had made toward implementing an e-pedigree for drug products and that we were optimistic that progress would continue in an expeditious manner toward meeting FDA's 2007 goal of widespread use of e-pedigree across the drug supply chain;
- If it appeared that the 2007 goal would not be met, we planned to consider options for implementing the provisions of the PDMA rulemaking that are the subject of the stay; and
- FDA would identify what we could do to address obstacles to the widespread adoption of RFID.

C. 2006 Fact-finding Efforts: Public Workshop, Vendor Display, and Docket

As the Task Force continued to monitor the adoption and implementation of e-pedigree and electronic track and trace technology, we recognized that adoption across the U.S. drug supply chain was slower than originally anticipated. To determine whether widespread use of e-pedigree by 2007 was still feasible, and to solicit comment on the implementation of certain PDMA-related regulations, we held a public meeting on February 8 and 9, 2006.[5] Our objectives for the meeting were to:

- Identify incentives for, as well as any obstacles to, the widespread adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles;
- Solicit comment on the implementation of the pedigree requirements of the PDMA and the use of an e-pedigree; and
- Learn the state of development of electronic track and trace and e-pedigree technology solutions.

Over 400 people attended the public meeting. Forty-six presentations were made and 27 vendors participated in the vendor display.

Members of the drug supply chain, the technology sector, special interest groups, academia, health professionals, and consumers also filed sixty comments to the public docket that we opened as part of the public workshop.

In addition, we have been attending conferences, meeting with stakeholders, tracking the status of pilot programs, monitoring changes in and use of technologies, participating in standards development, and closely following other influences to remain up-to-date on the relevant issues.

This report is based primarily on information gathered from these fact-finding efforts. It contains our views on outstanding issues related to e-pedigree and RFID implementation, as well as recommendations for additional public and private measures to support our continuing efforts to further secure our nation's drug supply.

III. WHAT IS NEXT FOR PDMA IMPLEMENTATION?

What should FDA do regarding the stay of 21 CFR §§ 203.3(u) and 203.50?

Issue/Background

The PDMA as modified by the Prescription Drug Amendments of 1992 (PDA) amended the Food, Drug, and Cosmetic Act (the Act) to, among other things, establish requirements related to the wholesale distribution of prescription drugs. Section 503(e)(1)(A) of the Act requires that

> "...each person who is engaged in the wholesale distribution of a drug***who is not the manufacturer or authorized distributor of record of such drug *** provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)"

PDMA defines an authorized distributor of record as a wholesaler that has an "ongoing relationship" with the manufacturer to distribute the drug. However it does not define "ongoing relationship."

In December 1999, the Agency published final regulations (1999 final rule) (21 CFR part 203) related to the PDMA[6] that were to take effect on December 4, 2000. After publication of the final rule, the Agency received communications from industry, industry trade associations, and members of Congress objecting to the requirements in 21 CFR §§ 203.3(u) and 203.50. These provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" (ADR), set forth requirements regarding an identifying statement (commonly referred to as a "pedigree"), and define the fields of information that must be included in the pedigree. Those objecting to the regulations explained that some secondary wholesalers may not receive pedigree information from their suppliers who meet the PDMA's definition of "authorized distributor" because the PDMA does not require authorized distributors to provide pedigree information. Without this information, they explained, secondary wholesalers would not be able to sell the drugs because they would be unable to pass a pedigree that met all the requirements of 203.50. Many secondary wholesalers are small businesses and expressed concern that their inability to meet the regulations' requirements would frustrate sales and drive them out of business.

Based on the concerns raised, the Agency delayed the effective date for those provisions until October 1, 2001[7] in order to reopen the comment period for the regulations and receive additional comments. In addition, the House Committee on Appropriations (the Committee) requested that the Agency review the potential impact on the secondary wholesale pharmaceutical industry and prepare a report to the Committee summarizing the comments and issues raised and the Agency's plans to address these concerns. The Agency's report, which was submitted to Congress in June 2001 (2001 PDMA Report to Congress), concluded that we could address some of the concerns raised by the secondary wholesale industry through regulatory changes, but that some of the changes requested by the secondary wholesale industry would require statutory change.[8] Since submitting the report to Congress, FDA has continued to delay the effective date of these provisions.

In February 2004,[9] FDA again delayed the effective date of the particular provisions until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would adopt electronic track and trace technology by 2007. When widely adopted, this technology could create a de facto e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, e-pedigree could meet the statutory requirements in section 503(e) of the Act.

In our 2006 fact-finding effort, we sought comment on whether to continue the delayed effective date, let the regulations go into effect, amend the 1999 final rule, or take other steps.

What We Heard

Most of the comments[10] to our February 2006 notice advised FDA to implement the regulations and let the stay expire. Some said the regulations should be implemented as currently written, without amendment. Others suggested amending the final rule to either 1) exempt the passing of pedigree along primary supply chain routes or the "normal chain of distribution," or 2) phase-in implementation, starting with requiring pedigrees for those drugs that are susceptible to counterfeiting and diversion, or 3) require a pedigree for "one forward-one back" in the distribution chain (as opposed to a pedigree that documents all prior sales transactions back to the manufacturer). A couple of comments suggested that we extend the stay in order to give industry more time to continue moving toward adoption of electronic track and trace technology and e-pedigree. A few wanted the stay to be extended in order to give time to amend the regulations. The amount of time requested for extending the stay varied from 5 years to indefinitely. We also received one citizen petition from a secondary wholesalers' trade association requesting that the stay be extended.

Some comments suggested that FDA work with Congress to eliminate the provision exempting the authorized distributor of record from having to pass a pedigree. They claimed that it was too confusing to recognize when a pedigree should or should not be passed.

Several comments asserted that implementation of the PDMA regulations would speed the development of new, less expensive ways to provide pedigree.

Discussion

We carefully considered several options and recommend that FDA no longer delay the effective date of §§203.3(u) and 203.50 past December 1, 2006. Regulations defining "ongoing relationship" and "authorized distributor of record" are scheduled to go into effect thereafter. In our 2006 fact-finding efforts, we gave stakeholders and the public ample opportunity to provide their input, but we did not hear the same arguments that we heard on previous occasions regarding why we should further extend the stay. Rather, this time, an overwhelming majority of the comments favored allowing the stay to expire.

The PDMA was signed into law in 1988. We believe that FDA can no longer justify delaying implementation of these regulations. In its 2001 PDMA Report to Congress, FDA shared the concerns that were raised regarding implementation of the regulations. By recommending implementation of the stayed provisions, we are supporting the law that Congress passed and has since retained. Furthermore, our extensive experience with counterfeit and diversion drug cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Allowing the stay to expire will provide clarity in the drug supply chain regarding who is and is not an ADR, requiring those secondary wholesalers who may be involved in illegal activity to provide pedigrees. Continuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to flourish.

We do not intend to put secondary wholesalers out of business. We continue to be sensitive to the concerns that they raised several years ago, even though we did not hear these concerns during our current fact-finding effort. Therefore, as explained below, we recommend that FDA take an enforcement approach that focuses on products most susceptible to counterfeiting and diversion, which should relieve some of the burden that secondary wholesalers might confront when these regulations go into effect.

Most of the comments we received in this fact-finding effort recommended that the regulations be implemented as is, while others advocated a phased-in approach, whereby the regulations would apply to a limited number of drugs at first. We agree that the regulations should be implemented as is. Many of the recommended changes to the pedigree requirements would require a change in the law. We believe that the regulations as currently written appropriately interpret and implement the PDMA, as Congress intended.

Although the regulations do not provide for a phased-in approach, we propose that FDA publish a Compliance Policy Guidance (CPG) before the stay expires that will contain a list of factors for FDA field personnel to consider in focusing their efforts when carrying out their duties in enforcing the law. We propose that these factors reflect a risk-based approach in which FDA uses its limited resources to focus on drug products that are most vulnerable to counterfeiting and diversion. We do not propose the creation of a list of drugs that meet the criteria, but instead suggest that the CPG provide examples. However, we recommend that FDA not limit its enforcement to just those drugs that meet the factors. Rather, the factors would merely provide guidance for where our field personnel should target their enforcement efforts. The factors to consider for the enforcement focus may include drugs with a high value in the U.S. market, drugs with prior indicators (such as drugs that were involved in diversion cases or counterfeiting), and drugs that are easily counterfeited.

We believe that this CPG would be considered a Level 1 guidance under FDA's good guidance practice (GGP) regulations. (21 CFR §10.115.) Therefore, we recommend that FDA publish a draft version for public comment, evaluate the comments, and then publish a final guidance by December 2006.

We recognize that complying with the stayed regulations may require changes in business practices. Compliance may also require implementation of additional information technology systems to generate a pedigree. Each of these processes may take time to achieve. However, we note that, although the regulations at issue have been stayed since 1999, the fundamental statutory

requirement to pass a pedigree has been in effect since PDMA was enacted. The regulations primarily serve to clarify who is an authorized distributor of record and what information a pedigree must contain. In addition, we believe that this report and the CPG we advocate herein will focus public attention on this issue such that any wholesalers who thought that they were not subject to the pedigree requirement will have adequate time to take appropriate steps to comply with the regulations.

Furthermore, many States have moved forward with their own pedigree requirements, which often contain requirements in addition to those in the PDMA. We are aware that stakeholders are preparing to meet these State requirements, both electronic (to meet California law) or otherwise. Consequently, they should be that much closer to meeting the federal PDMA requirements as well.

Recommendation:

- **We recommend that FDA not continue to delay the effective date of §§203.3(u) and 203.50 beyond Dece 1, 2006.**
- **We recommend that FDA issue a draft Compliance Policy Guide for public comment that would focus F pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion.**

IV. WHAT IS THE STATUS OF ELECTRONIC TRACK AND TRACE ACROSS THE DRUG SUPPLY CHAIN?

A. What is the progress of the use of e-pedigree in the drug supply chain?

Issue/Background

In the 2004 Task Force Report, we said that adoption and widespread use of reliable track and trace technology is feasible by 2007. We stated that this would help secure the integrity of the supply chain by providing an accurate drug "e-pedigree," an electronic record documenting that the drug was manufactured and distributed under secure conditions. We particularly advocated for the implementation of electronic track and trace mechanisms and noted that RFID is the most promising technology to meet this need.

In our 2006 fact-finding effort, we sought comment on the progress of e-pedigree implementation in the drug supply chain to determine if the goals outlined in the 2004 Task Force Report would be met.

What We Heard

Several comments described completed and ongoing pilot programs for e-pedigree and their successful deployment of e-pedigree in a real-time production environment. Most pilot programs involved distribution with one manufacturer, one wholesaler, and, in some cases, one pharmacy. Many comments stated that e-pedigree can be achieved using either RFID or barcodes. A number of comments stated that standards for e-pedigree are complete and that interoperable software is available. A few comments from manufacturers of already-serialized products said that they have developed track and trace systems capable of providing an e-pedigree through existing internet technologies.

Most comments agreed that it was necessary to adopt mass serialization with unique identifiers on each package as an important step to facilitate e-pedigree, while some comments stated that it is not needed. A majority of the comments stated that although widespread use of e-pedigree is not far off, it is hard to predict when that might happen or set a new timetable or a new target date. However, many comments suggested that FDA set a specific date by which all products must have an e-pedigree, arguing that without a specific date progress toward adoption will continue to be slow. Some comments recommended that FDA establish realistic phased-in compliance dates for adoption of e-pedigree.

Discussion

In 2004, we were optimistic that widespread implementation of e-pedigree was feasible by 2007 because we were told by many stakeholders in the drug supply chain that this was a realistic goal. Although significant progress has been made to set the stage for widespread use of e-pedigree, unfortunately, this goal most likely will not be met. We will not issue a new forecast or target date for adoption of e-pedigree because we do not have enough information to do so at this time. Most comments said that it is difficult to predict or designate a target date. We do believe that a timetable with achievable, realistic milestones is crucial to keep e-pedigree implementation on track. Therefore, we recommend that FDA continue to work with members of the drug supply chain to develop such a timetable.

We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps to implement an e-pedigree and States that have championed this cause, such as California. However, it is clear from our recent fact-finding efforts that the voluntary approach that we advocated in the 2004 Task Force Report did not provide industry with enough incentives to meet FDA's deadline. The mere "risk" of the PDMA regulations being implemented was not enough of an incentive. When PDMA was enacted, the state of technology was not as advanced as it is today, and, as a practical matter the industry could pass only paper pedigrees.

We understand the complexity in moving toward an e-pedigree and recognize that a hybrid approach using both paper and electronic pedigrees will be needed during a transition period. We continue to believe that RFID is the most promising technology for electronic track and trace across the drug supply chain. However, we recognize that the goals can also be achieved by using other technologies, such as 2D-barcodes. Based on what we have recently heard, we are optimistic that this hybrid environment of electronic/paper and the use of RFID/bar code is achievable in the very near future. We believe that efforts to ensure that hybrid pedigrees are secure and verifiable should be a priority consideration.

If legislation is considered in Congress related to e-pedigrees, we stand ready to provide technical assistance.

Recommendation:

- **We recommend that stakeholders work cooperatively to continue to expeditiously implement widespre use of electronic pedigrees across the drug supply chain.**
- **We recommend that FDA provide technical assistance if legislation related to electronic pedigrees is considered in Congress.**

B. What is the progress of the use of RFID on drug product packages?

Issue/Background

We sought comment on the implementation status of RFID, including a description of the obstacles to widespread adoption, an estimate of the timetable, the suggested role of FDA, and the incentives needed to promote adoption.

What We Heard

A majority of the comments agreed that RFID is the most promising technology for track and trace in the drug supply chain. We received many comments describing current obstacles to wider adoption of RFID, including:

- A lack of standards (for e-pedigree fields and format, data systems, international transmission standards, and hardware specifications);
- Privacy concerns;
- Concerns about the ownership of confidential business transaction data;
- Challenges in serializing all products;

- Concerns over the accuracy and speed of electronic devices and systems; and
- A lack of definitive data to determine how RFID will affect sensitive products (e.g., liquids, biologics).

Many comments stated that it is not possible to predict or estimate a timetable for widespread adoption of RFID, or stated that widespread RFID adoption is at least many years away. Some comments estimated that it will take up to 10 years. Many comments suggested that technical issues (e.g., adoption of standards, product/software development) would need to be settled before a more accurate timetable could be estimated. A number of comments suggested a phased-in approach for RFID adoption to provide industry sufficient time to explore all options. One comment from a stakeholder closely involved in the development of RFID technology stated that the FDA timeline for RFID adoption is technically feasible, that is, widespread adoption of RFID is feasible by 2007.

Comments noted that progress toward the full adoption of RFID technology is occurring, but that adoption is moving more slowly than previously anticipated. Several pilot projects have been conducted or are underway to test the feasibility of RFID deployment along the prescription drug supply chain, but data is limited.

Most comments said that FDA should not mandate or require the use of RFID in the drug supply chain. Instead, some comments said that FDA should continue to encourage the use of RFID. Many comments said that FDA should actively participate in, support, and facilitate RFID activities, especially those activities of groups working to establish RFID standards and implementation. In addition, many comments said that FDA should take a lead role in developing a public education program about the use of RFID technology on drug products.

Most comments said that incentives would help in the adoption of RFID across the supply chain. Only one comment said that no incentives are needed. Comments suggested the following incentives:

- Financial/tax incentives;
- Mandating mass serialization on drug products, but allowing industry to determine the most appropriate technology to ensure compliance;
- Statutory changes.

Discussion

We continue to believe that RFID is the most promising technology for implementing electronic track and trace in the drug supply chain and that stakeholders should move quickly to implement this technology. We appreciate the candid views and concerns that were shared with us during this fact-finding effort in identifying obstacles to implementation. Within this report, we have tried to address the issues related to those obstacles that are within FDA's purview.

Although we are encouraged by the efforts of GlaxoSmithKline, Pfizer, and PurduePharma in tagging their products, and the efforts of many other companies and wholesalers in exploring and piloting RFID, we are disappointed with the lack of overall progress across the drug supply chain. In the 2004 Task Force Report, we laid out milestones and goals for RFID implementation based on credible information that stakeholders gave us. Many of these milestones have not been met. The technology vendors uniformly told us that their RFID and e-pedigree solutions and technologies are ready to go, but manufacturers, wholesalers, and retailers are slow to implement them.

We recognize that progress may have been delayed because standards have not yet been established. However, we are encouraged by the progress that industry has made to develop and adopt universal standards. Based on what we heard, those standards are close to completion. Once completed, we would expect to see a rapid growth in the implementation of RFID in the drug supply chain. We look forward to continuing to participate and support this standards development process.

In November 2004, FDA issued a CPG for conducting pilot studies for RFID tagging. In that CPG, FDA excluded biological products as eligible for these pilot studies because we had insufficient

information about the impact of radio-frequency (RF) on biologics. To date, we have not received sufficient information to change this policy. Therefore, the CPG continues to remain in effect as written until December 31, 2007. In order to further our understanding of the impact of RF, we have begun our own study to evaluate the potential impact of RFID on drug and biological products. We expect to share the results of this study later this year.

We recognize that implementing an RFID-enabled drug supply chain is challenging. We appreciate the comments advocating a phased-in approach and urge manufacturers to take a risk-based approach to implementation by first tagging the products that are most vulnerable to counterfeiting and diversion, based on factors such as the sales price, volume sold, demand, ease of counterfeiting, and prior history of counterfeiting or diversion, among other things. If a company's products are not "at risk", then we would suggest the company choose its highest volume/highest sale drug(s) and start piloting. Although RFID deployment does have significant start up costs, based on our discussions and what we heard, most stakeholders agree that there are also significant benefits. Not only does the track and trace capability of RFID provide anti-counterfeiting and supply chain security benefits, but it also offers significant savings in the form of better inventory management, reduction in theft and product loss, improved recall efficiency, and reduced paperwork burdens.

RFID also has tremendous potential benefits for drug products used in public health emergencies, such as a pandemic influenza or a bioterrorist attack. RFID tracking could help in expeditious deployment and redeployment of medical countermeasures in times of crisis. FDA should, therefore, encourage manufacturers of these types of products to explore the use of RFID.

We agree with the comments that FDA should not mandate RFID. Although in 2004, we sought voluntary adoption and more widespread use by 2007, we believe that the private sector momentum is moving and that our input on some of the perceived obstacles may jumpstart further adoption interest and momentum. In the 2004 Task Force Report, we laid out a timetable for mass serialization and RFID implementation, as well as steps for businesses and standard-setting issues. Although the timetable goals were not met, we continue to stand by this approach and are prepared to work with stakeholders who wish to take the lead in developing a new, feasible, yet ambitious, timetable.

Recommendation:

- **We recommend that stakeholders continue moving forward in implementing RFID across the drug supp chain.**
- **We recommend that stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.**
- **We recommend that FDA remain committed to facilitating RFID implementation and working with stakeholders, standards organizations, and others.**
- **We recommend that FDA work quickly to complete its RFID Impact Study examining drugs and biologic and publicly share the results.**
- **We recommend that stakeholders explore the use of RFID for tracking medical countermeasures.**

V. WHAT TECHNICAL ISSUES RELATED TO ELECTRONIC TRACK AND TRACE NEED RESOLUTION?

1. Mass Serialization

Issue/Background

Mass serialization involves the incorporation of a unique identifier number on each drug package in order to track the individual drug package as it moves through the drug supply chain. We sought comment on mass serialization numbering schemes, including the preferred numbering convention, the merits of incorporating the National Drug Code (NDC) number and its impact on patient privacy, and the timetable for mass serialization across the drug supply chain.

What We Heard

Almost all the comments recommended that industry use a single numbering convention to reduce costs and complexity. One comment noted that multiple numbering schemes could lead to conflicts (e.g., duplicate numbers for the same item) and incompatibility between points in the distribution chain. Several comments suggested that using random numbers for the product identification component of the electronic product code (EPC) could increase security, while concealing proprietary information about the product or manufacturer. However, other comments suggested that the EPC should include the manufacturer ID as part of the code.

Many comments addressed whether or not the NDC should be included in the unique identifier. Many comments were concerned that RFID tags could be surreptitiously read, and if the NDC was included, it could jeopardize the privacy of patients and potentially endanger the drug supply chain. However, pharmacies and their trade groups supported the inclusion of the NDC, arguing that their information systems currently identify products by using the NDC and that they might incur significant costs to change these systems if they used an EPC that did not include the NDC. Some of these comments also noted that the NDC plays an important role in the dispensing process and it would be disruptive to workflow to have to consult another database to link the EPC number to the NDC number. However, a couple of the comments noted that it is not necessary to include the NDC as a component of the unique identifier because, pursuant to FDA regulations (21 CFR §§ 201.2 or 201.25), the NDC is printed on most drug packaging.

Finally, several comments from stakeholders that are closely involved in developing the EPC standards suggested that the numbering convention be sufficiently flexible to accommodate standards-based numbering systems already in use (e.g. NDC for pharmaceuticals, UID for U.S. Department of Defense, EAN.UCC for consumer goods.)

Discussion

We continue to believe that using mass serialization to uniquely identify all drug product packages in the U.S. is a powerful tool in securing the nation's drug supply. The issues surrounding which numbers should be included in this unique identifier are complex. The NDC number is ubiquitous as an identifier of drug products for inventory, dispensing, and claims adjudication, among other things. However, because it is such a recognized number, an NDC number could compromise patient privacy and supply chain security if it could be read surreptitiously.

We believe that the NDC number is an important product identifier and it should be closely associated with the product. We note that, currently, for most prescription drug product packages, the NDC number is either printed on the packaging or included in a bar code on the package. We do not anticipate this practice to change.

We also recognize that inappropriate access to the NDC number on individual products raises patient privacy and security issues. These competing concerns, however, can be addressed through IT solutions. Therefore, we believe that for drug product packages using RFID or other non-line-of-sight technologies, the unique identifier should either include an encrypted NDC number or provide an accessible link to the NDC number that is readily available to pharmacies to facilitate their needs.

Ideally, there should be one numbering scheme used in the drug supply chain. We recognize that the technology continues to advance and it is difficult to predict what its capabilities will be in the near future.

Recommendation:

- **We recommend that the NDC number should continue to be closely associated with the product.**
- **We recommend that for non-line-of-sight technology, such as RFID, the unique identifier for the produc should either include an encrypted NDC number or an accessible link to the NDC number to protect pri**

2. Universal Pedigree and Uniform Pedigree Fields

Issue/Background

The PDMA limits who is required to pass a pedigree and authorizes FDA to determine what information should be included in the drug pedigree. This information is codified at 21 CFR 203.50. Some States have laws imposing pedigree requirements on members of the drug supply chain not covered under the PDMA. Some States have enacted laws requiring additional information to be included in pedigrees passed with drugs sold in their State. In addition, State requirements differ with respect to the information that must be included in the pedigree. We sought comment on what information pedigrees should contain and how such a uniform standard could be achieved.

What We Heard

Nearly all comments encouraged FDA to implement federal uniform pedigree requirements and standards binding on the drug supply chain and States. Several comments noted the work of stakeholder initiatives, including the Uniform Pedigree Task Force and the EPCglobal e-pedigree standards working group. These stakeholder initiatives suggested data fields that could be captured in a uniform pedigree, including:

- Product Information: drug name, manufacturer, product NDC, dosage form, strength, container size;
- Item Information: lot number and expiration date, quantity of units by lot, product serial number (if serialized);
- Transaction Information: transaction identifier (e.g., PO, invoice) and date, transaction type (e.g., sale, transfer, return), date received;
- Trading Partner Information: business name, address and license of seller, alternate ship-from location of seller, seller contact information for authentication, business name, address and license of recipient, alternate ship-to location of recipient;
- Signatures/Certifications: digital signature of seller, digital signature of recipient.

There was near complete agreement that all wholesalers, not just non-authorized distributors, should be responsible for passing pedigree information. Many of these comments urged FDA to take appropriate steps to require a universal and nationally uniform e-pedigree so that stakeholders do not have to comply with 50 different State pedigree requirements.

Discussion

The PDMA requires a statement/pedigree ("in such form and containing such information as the Secretary may require") to be passed with certain wholesale distributions. The PDMA and FDA's pedigree-related implementing regulations define the information that must be included in a pedigree.

We continue to believe that a universal e-pedigree (i.e., a pedigree passed by all wholesalers, not just those who are not authorized distributors of record) that documents the movement of every prescription drug product from the manufacturer to the dispenser would be an important step in preventing counterfeit drugs from entering the drug supply chain.

We also agree with the comments that a single, national, uniform pedigree would be ideal to help ensure efficient distribution of safe and effective medicines. To be most effective and efficiently communicate chain of custody and other information about the drug product, it would be ideal if all members of the drug supply chain passed a pedigree that was uniform across all States. Fifty different State pedigrees will no doubt create confusion in the marketplace and could stifle interstate drug trade. For example, the pedigree laws that were enacted in Florida, California, Indiana, and other States contain different requirements.

Under existing law, FDA lacks statutory authority to implement a universal and nationally uniform pedigree. If legislation is considered in this area, we stand ready to provide technical assistance.

Recommendation:

- **We recommend that FDA provide technical assistance if legislation in this area is considered in Congre**

3. Data Management/Data Security

Issue/Background

For e-pedigree transmission to be successful throughout the drug supply chain, business partners at each point in the supply chain should be able to share information effectively and efficiently. The choice of data management practices and standards becomes an important one for all stakeholders. One issue that has been raised is whether the data/information should be stored in one central database or if a distributed approach (where each stakeholder's system exchanges information with other systems) should be used.

What We Heard

A majority of the comments advocated the use of a distributed database approach to data management. Many noted that a centralized database would be more costly, slower to implement, a threat to patient privacy, and could disrupt drug distribution if the database was unavailable or compromised for some reason. Comments suggested that secure peer-to-peer transactions would be possible under the distributed model. One comment suggested that data management be controlled centrally via a third party, contractually-managed by FDA.

A few comments suggested specific data security measures, such as pedigree documents having digital signatures to maximize document integrity, authentication, and non-repudiation. Some comments referred to existing data transmission standards used elsewhere, specifically Public Key Infrastructure, Federal Information Processing Standards, and the ISO/ICE standards 17799 or 12207. One comment noted that e-pedigrees could be authenticated electronically, using electronic verification of the digital signature and the signed transaction content for each transaction. One comment promoted the use of biometric log-on methods to improve security.

Discussion

It is vital that specific event information contained in the electronic pedigree be secure. We have no preference as to whether the data is housed in a central database or in a distributed scheme. Based on what we heard, it is our understanding that e-pedigree is technologically feasible with either model and even in a hybrid environment, where some data is stored in a central database while other data is distributed across company servers. We believe it would be most efficient to let the market and technology dictate how to best capture and access the data in e-pedigrees.

We do believe that it is essential that every entity in a drug product's chain of custody has access to the product's pedigree data all the way back to the manufacturer, in order to verify and authenticate the pedigree. It is also important for FDA to have access to the information in matters of suspect illegal activity.

Recommendation:

- **We have no preference whether a distributed versus central database is used, as long as every entity in chain of custody for the product has access to information about that product all the way back to the manufacturer.**

4. Privacy Issues

A. Labeling/Disclosure/Education

Issue/Background

There is general concern that an unauthorized person might be able to read the information from an

RFID tag on a drug without the possessor of the drug knowing it, possibly disclosing personally identifiable information or the name of the drug. We sought comment on whether privacy concerns are warranted and whether it is possible for an unauthorized person to read the information from an RFID tag on a drug once that drug is in the consumer's possession. If so, what type of information could be accessed? We also sought comment on how to make consumers aware that an RFID tag is on the drug package and the type of consumer education that would be needed as the use of RFID in the drug supply chain becomes more prevalent.

What We Heard

The majority of the comments indicated that privacy safeguards are needed. However, some pharmaceutical organizations said that patient privacy issues are not a major concern because many of the prescriptions filled at pharmacies are not dispensed in the original bottles from the manufacturer; the prescriptions are instead placed in a consumer-size container, which would not have an RFID tag. Some comments cited concern about persons gaining unauthorized access to information about the type of drug being taken as well as personal identifying information. Several comments said that the RFID tag should not contain information that identifies the drug (e.g., NDC number). Instead, these comments suggested that the tag should contain a random serialized number so that anyone reading the tag would see only a meaningless number.

Many comments referred to the importance of consumer notice and choice and the use of fair information practices. Comments noted that notice of the presence of an RFID tag on a drug package should be clear, conspicuous, and accurate. Several comments indicated that one way to address the issue of consumer notice is to use a symbol on the package. There was uncertainty, however, as to where the symbol should be placed.

Some comments pointed out that many concerns about privacy are due to concerns about database security (i.e., once the data is collected from an RFID tag, how secure is the database where it is stored?).

The majority of comments said that consumer education is needed for the successful adoption of RFID across the drug supply chain. Many comments indicated that consumers should be informed of the benefits of RFID (e.g., how RFID can help secure the drug supply chain), as well as the risks associated with the technology (e.g., potential threat to privacy). According to some comments, consumers should also be educated about the options that are available for deactivating or removing the RFID tag. Most comments said that FDA, as well as experts in academia, industry, and patient and consumer groups, should be involved in developing education programs.

Discussion

Privacy issues are a real concern for consumers and FDA. These concerns will continue unless there is appropriate disclosure of the presence of an RFID tag on containers given to patients and sufficient education about the application, true risks, benefits, and vulnerabilities associated with RFID tags on drug products. This is no easy task.

Although we support the use of a statement or symbol to disclose the presence of an RFID tag on a drug product package, it is important that manufacturers work with FDA to develop an appropriate message or symbol. Most statements made on the labeling of prescription drug products are regulated by FDA and subject to agency pre-approval. We, therefore, recommend that manufacturers should work with FDA before choosing a statement or symbol to add to their product labeling.

We also are willing to work with stakeholders to develop a uniform statement or symbol that can be used to signal the presence of an RFID tag on a drug product package to use in educational campaigns. Such campaigns would help consumers to readily identify and understand the meaning of the statement or symbol.

We do not propose to issue guidance at this time regarding statements or symbols on drug product labeling to indicate the presence of an RFID tag.

Consumer education is necessary. Potential messages could include educating consumers about RFID, the benefits of its use for patient safety, the privacy risks, possible risks from RF emission, and deactivation and removal of the tag. We do not currently have the resources to lead educational efforts. However, we will work with manufacturers and other stakeholders in their efforts.

Recommendation:

- **We recommend that FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contai RFID tag.**
- **We recommend that FDA work with private and public sector organizations in their efforts to educate consumers about RFID.**

B. "Turning Off" the RFID Tag

Issue/Background

Some people have suggested that the RFID tag should be "turned off" or deactivated before it leaves the pharmacy, or that patients should be given the choice of whether it is "turned off". We sought comment on the advantages, disadvantages, and feasibility of deactivating the tag.

What We Heard

Many comments indicated that deactivating or removing the RFID tag at the point of purchase (i.e., the pharmacy) would effectively address privacy concerns. However, some comments pointed out that while deactivating or removing the tag would address privacy concerns, it may also prevent post-sale benefits (e.g., recalls) which would have been possible had the tag remained active/in place.

Some pharmacy groups said that the tag should be deactivated prior to arrival at the pharmacy retailer to ensure that no patient is inadvertently sent home with an active tag. One comment said that in practice, deactivating the tag at the point of sale is not feasible because it would place too much responsibility on pharmacists and may re-expose the drug to unknown radio-frequency effects. Some comments indicated that FDA should provide guidelines to ensure privacy protections through RFID tag deactivation or removal.

Many comments suggested various deactivation methods. Some of the suggested options were: kill function (total or partial), blocker chips, encryption, read protection, decommissioning with individual tag password, tag destruction, placing RFID tagged objects in a foil lined bag (which would prevent unwanted reads), and database controls. There was no consensus on the best deactivation method. However, a standards organization commented that it is evaluating tag deactivation, taking into consideration the consumer and industry benefits of post-sale uses of RFID tags. The point in the supply chain where RFID tags should/could be deactivated is also being evaluated.

Discussion

There are benefits to both keeping the RFID tag active after sale and deactivating it before dispensing the product. We believe that an active tag can provide valuable information if the drug product finds its way back into the drug supply chain. FDA has found counterfeit and diverted drugs in the drug distribution system when drug wholesalers, third-party return entities, or manufacturers return drugs for credit and/or destruction. Those products with active tags would be easier to identify and track through the supply chain. That said, we respect the privacy concerns, however, and do not believe that it is necessary for an active tag to go to the patient.

It is unclear whether technological methods to deactivate the tag in the normal course of business are mature enough for use in the marketplace at this time. We believe that this issue warrants further discussion among stakeholders, technology experts, and consumers, about the viable options and we are not prepared to make a recommendation at this time.

Recommendation:

- **We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time.**

CONCLUSION

FDA's vision of a safe and secure drug supply chain is premised on transparency and accountability by all persons who handle the prescription drug, starting with the manufacturer and ending with the pharmacist who hands the drug over to the patient. Drug supply chain efforts that capitalize on advances in electronic track and trace technology to create a secure electronic pedigree further this vision.

With the implementation of the PDMA regulations in December 2006, we expect that supply chain stakeholders will move quickly to adopt electronic track and trace technology, implementing RFID in a phased-in approach. We recognize that there are important issues that still need resolution, such as privacy concerns and uniform and universal pedigrees that might benefit from further discussion by stakeholders or Congress. However, these issues should not hinder the forward progress and momentum toward widespread adoption that we have witnessed and expect to continue. Companies should continue to tag drug products, build infrastructure across the supply chain for using an e-pedigree, and remain vigilant in their responsibility to provide a safe and effective drug product to the patient.

Footnotes

[1] The Task Force consists of senior staff from the Office of the Commissioner (Office of Policy and Planning, Office of the Chief Counsel), Office of Regulatory Affairs, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

[2]The FDA Counterfeit Drug Task Force recommendations are detailed in its report, entitled, "*Combating Counterfeit Drugs – A Report of the Food and Drug Administration* ," February 18, 2004 (2004 Counterfeit Drug Report) (http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html).

[3] PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the Prescription Drug Amendments (PDA) (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 333, 353, and 381) to, among other things, establish requirements related to the wholesale distribution of prescription drug products.

[4]*Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update* , May 18, 2005 (http://www.fda.gov/oc/initiatives/counterfeit/update2005.html).

[5]The workshop agenda, speakers' presentations, and meeting transcript are available at www.fda.gov/rfidmeeting.html .

[6]64 FR 67720.

[7]65 FR 25639.

[8]See http://www.fda.gov/oc/pdma/report2001/

[9]69 FR 8105.

[10]In this report, the term "comments" includes comments that we heard at the public meeting and written comments submitted to the docket.

Counterfeit Drugs Home Page

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA | Privacy | Accessibility

FDA Website Management Staff